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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,533	11/14/2001	Kiamars Hajizadeh	3873 P 006	4433

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EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/992,533	HAJIZADEH ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45 & 78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-45 and 78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 46-77 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

2. Applicant's election with traverse of claims 1-45 and 78 in the reply filed on August 5, 2004 is acknowledged. The traversal is on the ground(s) that it would not be a serious burden on the examiner to search and examine all of the claims together. This is not found persuasive because the inventions have been shown to be distinct by the office and acknowledge by Applicant, therefore a search and examination for the device group I is not co-extensive with the test kits of Group II.

The requirement is still deemed proper and is therefore made FINAL.

3. This application contains claims drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

4. Claims 1-3, 7, 11-23, 26, 30-33, 35, 36, 39-45 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korth et al (US 6,765,088 B1) in view of Sy (WO 98/33069).

Korth discloses test kits for the diagnosis of prion diseases comprising devices and materials enabling the diagnosis of prion diseases. One particular test kits comprises one or more monoclonal antibodies coated on nitrocellulose sheets or microtiter plates; a secondary anti-mouse antibody that is labeled with an enzyme, and its substrate or any other molecular compound for a detection reaction, hydrogen peroxide, proteinase K, a blocking buffer, a

homogenization buffer, a calibration curve and a description of how to perform the test. See column 13, lines 17-33. Korth also disclose another test kit designed in the dipstick format and taught it as providing the advantage of reducing the number of handling steps to one. The one step procedure involves the capture of the disease specific PrP^{Sc} with one antibody immobilized on a test strip. Captured PrP^{Sc} is detected directly by a second antibody coupled to colloid particles.

Korth differs from the instant invention in failing to specifically teach that the dipstick comprises a digestive pad having proteinase K immobilized therein or that the labeled antibody is disposed in a conjugate pad.

However, Sy teaches an assay device for the detection of analytes comprising a sample preparation zone having immobilized therein acids or alkalis to adjust the pH, buffers to stabilize the pH, chelating agents, surfactants and hydrolytic enzymes, etc. The device also includes a conjugate zone having labeled specific binding partner, and a detection zone comprising an immobilized capture binding partner. See pages 15 and 18.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Korth to include a digestive pad having appropriate enzyme reagents (e.g. proteinase K) as taught by Sy because such a device provides the advantage of reducing the number of handling steps (Korth, column 13, line 36), and further enable the sample to be prepared directly so as to eliminate the need for extraction vessels and transfer devices (Sy, page 4, lines 3-12). Since Korth teaches that PrP^{C} and PrP^{Sc} are more readily distinguished according to their different sensitivity to digestion with proteinase K, and their use to digest tissues specimen is preferred (column 15, example 1), a skilled artisan would have had a reasonable expectation of success in modifying the device of Korth to include a

digestive pad as taught by Sy in order to provide a more convenience device for distinguishing between PrP^C and PrP^{Sc}, and to further include a conjugate pad containing labeled antibody because Sy teaches that such a device is well known in the art (page 2, lines 17-31). In addition, Sy teaches that a device comprising a sample preparation device (i.e. a digestive pad) provides the advantage of an improved assay device by avoiding false negatives and false positives.

Even though Korth in view of Sy does not specifically teach the covalent immobilization of proteinase K in the digestive pad, such an immobilization procedure is well known in the art and would have been obvious to a skilled artisan. Since Applicant has not disclosed that covalent immobilization of the proteinase K in the digestive pad is for any particular purpose or solve any stated problem, and the prior art teaches that such reagents often vary according to the sample being analyzed, and various matrices, solutions and parameters appear to work equally as well, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures known in the art.

5. Claims 9, 10, 28, 29, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korth in view of Sy as applied to claims 1-3, 7, 11-23, 26, 30-33, 35, 36, 39-45 and 78 above, and further in view of Hope et al (WO 00/29850).

See the discussion of Korth and Sy above. These references differ from the instant invention in failing to teach the specific amount of proteinase K in the digestive pad.

Hope, however, discloses that digestion of prion containing samples with increasing concentration of proteinase K (PK) improves the detectability of prions. See page 24. Hope teaches PK concentration in the range of 0 μg/ml to 100 μg/ml. Hope teaches the PK extraction

procedure digests PrP^C and facilitates the measurement of PrP in the primary and secondary extract.

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to include an appropriate amount of PK, as taught by Hope, in the device of Korth as modified by Sy because Korth and Sy teaches that by providing proteolytic enzymes on a test strip a device having the advantage of reducing the number of handling steps is obtained, and because Hope teaches that PK effect is achieved by the addition of appropriate concentrations of PK.

6. Claims 4-6, 8, 24, 25, 27 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korth in view of Sy as applied to claims 1-3, 7, 11-23, 26, 30-33, 35, 36, 39-45 and 78 above, and further in view of Sundrehagen (US 6,716,641 B1).

See the discussion of Korth and Sy above. These references differ from the instant invention in failing to teach that the proteinase K is immobilized on solid phase particles and disposed in the digestive pad.

Sundrehagen discloses a dipstick device for detecting and quantifying a target analyte. Sundrehagen teaches a screening zone for removing non-target variants from the sample being analyzed leaving only the target variants to pass through to the detection zone. Sundrehagen teaches specific binding partner coated on latex particles or gel particles disposed in the screening zone. See column 6, lines 23-42; column 9, lines 27-59.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the latex particles taught by Sundrehagen in the device of Korth as modified by Sy to carry the proteinase K because Sundrehagen teaches that the use of

additional pad or solid phase particles carrying screening reagents provides the advantage of a large surface area for immobilizing the necessary amount of reagents. (See column 9, lines 43-45)

Even though Sundrehagen does not specifically teach that the particles are of a specific dimension, Sundrehagen does teach that the particles should be larger than the pore size of the pad in order to ensure that they are not released from the pad (column 9, lines 63-65), therefore, a skilled artisan would have had a reasonable expectation of success in choosing the appropriate particles for use in the device of Korth as modified by Sy above.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,141,850

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. - 3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BAO-THUY L. NGUYEN
PRIMARY EXAMINER
8/30/04